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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,020	12/19/2001	Esha A. Gangolli	21402-225 (Cura-525)	3246

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EXAMINER
CARLSON, KAREN C

ART UNIT	PAPER NUMBER
1656	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/19/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/029,020	GANGOLLI, ESHA A.	
	Examiner	Art Unit	
	Karen Cochrane Carlson, Ph.D.	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *June 30, 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5,9,10,39,42 and 50-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5,9,10,39,42 and 50-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the paper filed June 30, 2006. Claims 5, 9, 10, 39, 42 and 50-59 are currently pending and are under examination.

Withdrawal of Rejections:

The rejection of Claims 5, 9, 10, 51-53 and 57-59 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, is withdrawn. The variants claimed are described at page 294 of the specification.

The rejection of Claims 10 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn.

The rejection of Claim 5 and dependent claims 10, 12-14, 39, 42, 50-53 are rejected under 35 USC 102(b) as being anticipated by Oohashi et al. ("Mouse Ten-m/Odz is a new family of dimeric type II transmembrane proteins expressed in many tissues," The J. of Cell Biology, vol 145, No. 3, pp 563-577, May 3, 1999), is withdrawn.

Maintenance of Rejections:

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title"

Claims 5, 9, 10, 39, 42 and 50-59 are again rejected under 35 U.S.C. 101 because the specification does not provide either a specific or substantial asserted utility or a well-established utility, and thus, does not support the claimed invention. The claimed nucleic acids are not supported by either a specific asserted utility or a well established utility because the specification fails to assert any utility for the claimed nucleic acids or the encoded proteins and neither the specification as filed nor any art of record disclose or suggest any activity for the claimed nucleic acids or the encoded proteins such that another non-asserted utility would be well established. Note, because the claimed invention is not supported by a specific asserted utility for the reasons set forth above, credibility cannot be assessed. The reasons are as follows:

The specification, on page 10, Table A describes protein designated as NOV4, set forth in SEQ ID NO: 14 encoded by the nucleic acid sequence of SEQ ID NO: 13 (NOV4, Table A) to which the instant invention relates. The NOV4, which has the 8354 of nucleotide sequence of SEQ ID NO: 13 (page 48+, Table 4A) that encodes a polypeptide having amino acid sequence of SEQ ID NO: 14 (page 50+, Table 4B). The specification further indicates at page 11 that the NOV4 is homologous to the TEN-M4-like family of proteins, thus the NOV4 nucleic acids, polypeptides, antibodies and related compounds will be useful in therapeutic and diagnostic application, which is associated with various diseases and disorders. Examples of many diseases have been listed (page 11-12, 65-67 and 189-192) but the specification does not indicate explicitly the correlation of the role of any composition comprising NOV4 to a specific disease treatment or prevention. Also, a homology to the TEN-M4-like family of proteins does not conclude that NOV4 polynucleotide encoding NOV4 polypeptide would be useful in therapeutic application for the treatment or prevention of cancer, inflammation, neurological disorders, metabolic disorders and other pathologies/disorders (see page 11 first paragraph to page 12, first paragraph). The specification further indicates at page 52 that the Table 4E lists the domain description from DOMAIN analysis results against NOV4, and on the basis of this results

specification indicates that the NOV4 sequence has properties similar to those of other proteins known to contain this domain. However, the specification fails to provide any function of these NOV4 sequences containing the said domain.

General uses of polynucleotides set forth in the specification, as filed include use to express encoded polypeptides, to screen a human cDNA or genomic library, to use as educational tools, genetic analysis, diagnostic applications, to use as probes and primers (pages 126-130), use for antisense nucleic acids (pages 136-138), therapeutic application (pages 189-192), screening and detection methods (pages 170-176) chromosomal mapping (pages 176-178), tissue typing (pages 178-179). These general uses are not specific and substantial, as they do not require any one particular sequence. There is no particular identifying information associated with the claimed nucleic acid molecule of the invention.

Based on the specification (pages 10-12, 48-67), any biological activity of the nucleic acid and encoded polypeptide itself has not been provided. However, generalized statements regarding uses have been provided on pages 126-130, 170-176 and 189-192 of the specification, but are discussed in the context of being used for further research, but to do what? The function/biological activity of the protein is not per se set forth in the instant specification. One skilled in the art should not have to engage in discovering genomics to learn how to use the invention. This situation requires carrying out future additional research to identify or reasonably confirm a "real world" context of use and therefore do not define specific and substantial utility.

Claims 5, 9, 10 drawn to a nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 13 encoding a polypeptide comprising an amino acid sequence selected from the group consisting of a mature form of the amino acid sequence of SEQ ID NO: 14 and variants, fragments and complements thereof (claims 50, 51-53 and 57-59);

However, the specification does not describe the functional properties of the polynucleotides of claims 5, 9, 51-53 and 57-59 and the structural information is limited. While the specification enumerates several known assays for biological activity (pages 170-176), it does not guide the selection of a specific assay that would be used to screen the biological activities of the claimed polynucleotides and polypeptides. Examples of many therapeutic methods have been described in pages 189-192 but the specification does not indicate explicitly the correlation of the role of the claimed polynucleotides and encoded polypeptides to a specific disease treatment. Moreover, specification fails to provide any information regarding molecules having TEN-M4 family activity.

Claims 12-14 are drawn to a vector/expression vector comprising the nucleic acid of claim 5, wherein the vector is introduced into host cells to express the protein (claim 14). Claims 54-56 are drawn to a vector/expression vector comprising the nucleic acid of claim 9, wherein the vector is introduced into host cells to express the protein (claim 56). Although a general description that includes host cells bacteria, yeast, fungal, insect and mammalian cell have been provided (159-163), specification fails to provide specific recombinant host cells comprising the claimed vectors that demonstrate expression of nucleic acid of SEQ ID NO: 13 of NOV4 clone.

Claims 39 and 42 drawn to a pharmaceutical composition comprising the nucleic acid sequence of claim 5, wherein the composition is contained in a kit (claim 42). The specification on pages 166-170 describes the compositions and kits containing the compositions but does not indicate the function of the nucleic acids and/or the expressed proteins therein. When the function of the nucleic acid or the encoded polypeptide is not known how one skilled in the art would know how to use the invention.

As discussed above, based on the specification it is unclear what activity the claimed nucleic acid molecule and polypeptides encoded therein possess and therefore unclear how a

person having skill in the art would be using the claimed polynucleotides and polypeptides encoded therein.

In the instant case, the failure of applicants to specifically identify why the claimed invention is believed to be useful renders the claimed invention deficient under 35 USC 101. No specific biological activity has been identified for the nucleic acid of SEQ ID NO: 13 and the encoded protein set forth in SEQ ID NO: 14 other than the fact that the protein may be a member of the TEN-M4-like family (page 11). The person having ordinary skill in the art would not be able to identify any specific activity for the protein comprising or related to SEQ ID NO: 14 based on its structure alone for the reasons set forth above. General statements that a composition has an unspecified biological activity or that do not explain why a composition with that activity is believed to be useful fails to set forth a "specific utility." Brenner v. Manson, 383 US 519, 148 USPQ 689 (Sup. Ct.1966) (general assertion of similarities to known compounds known to be useful without sufficient corresponding explanation why claimed compounds are believed to be similarly useful is insufficient under 35 USC 101).

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5, 9, 10, 39, 42 and 50-59 are also again rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and

substantial or well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention so that it would operate as intended without undue experimentation.

Applicants argue (page 5, para. 4 through page 6, para. 4) that the nucleic acid encoding NOV4 is useful for the detection of specific types of cancer; therefore, the nucleic acid has specific, substantial, and credible utility and is enabled. The specification at pages 11-12 lists all kinds of maladies that the nucleic acid encoding NOV4 could be useful in diagnosing.

This is the passage:

> NOV4 is homologous to the TEN-M4-1ike family of proteins. Thus, NOV4 nucleic acids, polypeptides, antibodies and related compounds according to the invention will be useful in therapeutic and diagnostic applications implicated in, for example: cancer, inflammation, neurological disorders, neuropsychiatric disorders, obesity, diabetes, viral/bacterial/parasitic infections, autoimmune diseases, renal artery stenosis, renal tubular acidosis, hypercalcemia, IgA nephropathy, Lesch-Nyhan syndrome, glomerulonephritis, interstitial nephritis, polycystic kidney disease, trauma, regeneration, Alzheimer's disease, allergies, addiction, anxiety, ataxia-telangiectasia, asthma, ARDS, atherosclerosis, behavioral disorders, aortic stenosis, atrial septal defect (ASD), atrioventricular (A-V) canal defect, ductus arteriosus, allergy, cerebral palsy, congenital adrenal hyperplasia, cirrhosis, cardiomyopathy, congenital heart defects, diabetes, diverticular disease, epilepsy, emphysema, endometriosis, endocrine dysfunctions, graft versus host disease, glomerulonephritis, graft versus host disease (GVHD), growth and reproductive disorders, hemophilia, hypercoagulation, hypercalceimia, Huntington's disease, hypertension, hypogonadism, idiopathic thrombocytopenic purpura, immunodeficiencies, interstitial nephritis, IgA nephropathy, lymphaedema, inflammatory bowel disease, leukodystrophies, multiple sclerosis, muscular dystrophy, myasthenia gravis, neurodegeneration, neuroprotection, obesity, Parkinson's disease, pain, polycystic kidney disease, pulmonary stenosis, pancreatitis, renal artery stenosis, renal tubular acidosis, stroke, systemic lupus erythematosus, scleroderma, subaortic stenosis, transplantation, tuberous sclerosis, Von Hippel-Lindau (VHL) syndrome, ventricular septal defect (VSD) and other diseases, disorders and conditions of the like.

See also pages 48-67 of the specification. Therefore, the specification does not specifically point out that the nucleic acid encoding NOV4 can be useful for diagnosing cancer. One skilled in the art would have to sift through the lists of potential uses the nucleic acid encoding NOV4 may have and find out for themselves which, if any, of these uses is truly viable.

Conclusion

No claims are allowed.

Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 571-272-0946. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Karen Cochrane Carlson PhD

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KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER